

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF COLUMBIA

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THE COALITION FOR MERCURY-FREE		)	
DRUGS, <u>et al.</u> ,		)	
		)	
	Plaintiffs,	)	
		)	
	v.	)	Civil Action No. 09-0015 (RBW)
		)	
KATHLEEN SEBELIUS, <sup>1</sup> SECRETARY		)	
OF HEALTH AND HUMAN SERVICES, <u>et al.</u> ,		)	
		)	
	Defendants.	)	
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**AMENDED MEMORANDUM OPINION<sup>2</sup>**

The plaintiffs, the Coalition for Mercury-Free Drugs (“Mercury-Free”), and several named individuals who are also the principal officers of Mercury-Free, bring this action against the Secretary of Health and Human Services and the Commissioner of the Food and Drug Administration (“FDA”) in their official capacities, alleging injuries arising from the defendants’ approval of the use of Thimerosal, a mercury-based chemical compound used in pharmaceutical products, such as vaccines, to prevent the growth of bacteria or fungi. See Complaint (“Compl.”) ¶¶ 3-7, 83-100. Currently before the Court are several motions, including the defendants’ motion to dismiss the plaintiffs’ complaint pursuant to Federal Rule of Civil Procedure 12(b)(1) on the

<sup>1</sup> Kathleen Sebelius, the current Secretary of Health and Human Services, and Margaret Hamburg, the current Commissioner of the Food and Drug Administration, have been substituted for the originally named defendants in this action pursuant to Federal Rule of Civil Procedure 25(d).

<sup>2</sup> This Amended Memorandum Opinion amends the Court’s June 29, 2010 Memorandum Opinion, specifically this footnote of the earlier opinion, based on the plaintiffs’ counsel’s representations that the April 1, 2010 docket entries were made by the Clerk’s Office, and therefore all of the supplemental submissions were timely filed. The Court therefore considered all of the supplemental submissions filed by the plaintiffs in rendering its decision, and the Clerk’s redocketing of the supplemental submissions after the Court’s initial March 31, 2010 Order did not accurately reflect that the information was timely filed. All of the supplemental information was therefore considered by the Court prior to the issuance of its ruling.

ground that the plaintiffs cannot allege a concrete, imminent injury caused by the defendants' actions sufficient to invoke the Article III jurisdiction of this Court, see Memorandum in Support of Motion to Dismiss ("Defs.' Mem.") at 2, which the plaintiffs oppose.<sup>3</sup> See Plaintiffs' Memorandum of Law in Opposition to the Defendants' Motion to Dismiss ("Pls.' Opp'n"). In addition to the defendants' motion to dismiss, the Court also considered the following pending motions and related filings in resolving the defendants' motion to dismiss: (1) the plaintiffs' motion to conduct jurisdictional discovery, see Plaintiffs' Motion for Leave to Conduct Jurisdictional Discovery ("Pls.' Mot. Re: Discovery"); Plaintiffs' Memorandum of Points and Authorities in Support of its Motion for Leave to Conduct Discovery Limited to the Issue of Jurisdiction ("Pls.' Mem. Re: Discovery"), which the defendants oppose, see Defendants' Opposition to Plaintiffs' Motion for Leave to Conduct Discovery Limited to the Issue of Jurisdiction ("Defs.' Opp'n Re: Discovery");<sup>4</sup> (2) the defendants' motion for a protective order, see Motion for a Protective Order; Memorandum in Support of Defendants' Motion for Protective Order; and (3) three motions by the plaintiff seeking leave to supplement the record, see Motion for Leave to Supplement Record [Oct. 9, 2009] ("Pls.' Mot. to Supplement I"), Motion for Leave to Supplement Record [Oct. 19, 2009] ("Pls.' Mot. to Supplement II"), Motion for Leave to Supplement Record [March 17, 2010] ("Pls.' Mot. to Supplement III"), which the defendants oppose, see Defendants' Opposition to Plaintiffs' Motions for Leave to Supplement

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<sup>3</sup> Because of their relevance to the issues raised in the defendants' motion to dismiss, the Court also considered the following documents in resolving the motion: the Defendants' Motion to Dismiss; the Reply Memorandum in Support of Defendants' Motion to Dismiss ("Defs.' Reply"); the Plaintiffs' Motion for a Preliminary Injunction ("Pls.' Mot. Re: Injunction"); the Memorandum of Points and Authorities in Support of Plaintiffs' Motion for Preliminary Injunction ("Pls.' Mem. Re: Injunction"); the Memorandum in Opposition to Plaintiffs' Motion for Preliminary Injunction ("Defs.' Opp'n Re: Injunction"); and the Plaintiffs' Motion for Leave to Conduct Jurisdictional Discovery.

<sup>4</sup> The Court also considered the Petitioners' [sic] Reply to Defendants' Opposition to Plaintiffs' Motion for Leave to Conduct Discovery Limited to the Issue of Jurisdiction ("Pls.' Reply Re: Discovery") in resolving the motion to dismiss.

the Record ("Defs.' Opp'n Re: Leave to Supplement"). For the reasons that follow, the Court finds that the plaintiffs do not have standing to bring this lawsuit and accordingly must grant the defendants' motion to dismiss the plaintiffs' complaint under Federal Rule of Civil Procedure 12(b)(1). In concluding that the plaintiffs lack standing, the Court considered their three motions for leave to supplement the record over the defendants' objection. The Court also concludes that the plaintiffs' request for jurisdictional discovery was not narrowly tailored to produce information relevant to the issue of standing and thus ordering jurisdiction discovery is not warranted. And because the plaintiffs' lack of standing, the Court finds that the issuance of a protective order is unnecessary.

## I. BACKGROUND

Thimerosal has been used in the United States since the 1930s and was subsequently determined by the FDA to be safe and effective when used as a vaccine preservative.<sup>5</sup> FDA, Thimerosal in Vaccines (March 31, 2010).<sup>6</sup> Nevertheless, in 1999, in furtherance of its overall aim to reduce all human exposure to mercury, the Public Health Service established a goal to remove Thimerosal from vaccines routinely recommended for children. See Defs.' Mem at 4. Consequently, there are now mercury-free alternatives for all vaccines routinely recommended for both children and adults. Id.

The plaintiffs oppose any use of mercury-based preservatives, such as Thimerosal, in vaccines contending that it is the cause of a variety of health problems, including the

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<sup>5</sup> It should be noted that vaccines that are packaged in single-dose vials do not require any preservative and thus will not contain any mercury-based preservative. See id., Ex. A, (FDA Citizen Petition Denial at 17). The presence of Thimerosal in vaccines is therefore only at issue where multi-dose vials are utilized, i.e., where multiple patients' doses are extracted from a common vial. See id., Exhibit A, (FDA Citizen Petition Denial at 4).

<sup>6</sup> Available at <http://www.fda.gov/BiologicsBloodVaccines/SafetyAvailability/VaccineSafety/ucm096228.htm> (last accessed April 21, 2010).

development of autism and other brain development disorders in children when either children or pregnant mothers are exposed to it. Compl. ¶¶ 68-73. On August 10, 2007, Mercury-Free filed a citizen petition seeking to have the FDA: (1) proscribe the use of Thimerosal-containing vaccines or other similarly preserved medical products for certain “susceptible” classes; (2) withdraw its approval of or revoke the license for the use of these vaccines; (3) issue an immediate recall and destruction of these vaccines; (4) alter the warning labels and informed consent policies for these vaccines; and (5) alter the FDA’s policy stance on these vaccines as a whole. See generally, Defs.’ Mem. at 1 (referring to the citizen petition, see Paul King, PhD, et al., Citizen Petition Requesting Certain Actions with Respect to Vaccines and Other Drug Products, Containing Added Mercury, in Order to Reduce the Health Risk to Susceptible Fetuses, Newborns, Children, Adolescents and Adults (Aug. 24, 2007), [http://mercury-freedrugs.org/docs/070824\\_CoMeDCitizenPetitionPart2.pdf](http://mercury-freedrugs.org/docs/070824_CoMeDCitizenPetitionPart2.pdf)). The FDA denied the petition on November 21, 2008, asserting that Mercury-Free’s contentions were supportable by neither law nor science and the pharmaceutical products currently on the market containing mercury preservatives are safe. Defs.’ Mem. at 1. Seeking to challenge the FDA’s denial of their petition, the plaintiffs filed their complaint with this Court.

The plaintiffs’ complaint “reiterates the arguments presented by [the p]laintiffs to the FDA and [the Department of Health and Human Services]” in Mercury-Free’s citizen petition and asserts that the defendants are in violation of federal law by not recalling or banning the use of mercury-based compounds in vaccines and other pharmaceutical products. Compl. ¶¶ 13, 87. The plaintiffs seek a prospective injunction requiring the defendants to suspend the approval and licensing of all products that contain mercury-based compounds, and requiring a recall of all batches of vaccines that contain Thimerosal unless its manufacturer can prove that its product

does not cause adverse neurological outcomes in any group of susceptible individuals. Id. ¶ 29-30. The defendants responded to the complaint with their motion to dismiss for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), on the basis that the plaintiffs lack standing to maintain their complaint. Defs.' Mem. at 2. Alternatively, the defendants seek dismissal under Federal Rule of Civil Procedure 12(b)(6) on the basis that their denial of the plaintiffs' citizen petition was neither arbitrary nor capricious and therefore was not in violation of the Administrative Procedure Act. Id.

After the defendants' motion to dismiss was filed, the plaintiffs sought a preliminary injunction to compel the defendants to ensure that Thimerosal-preserved influenza vaccines were not administered to pregnant women during the 2009-2010 flu season. Pls.' Mem. Re: Injunction at 3. The Court held a hearing on the plaintiffs' request on August 26, 2009, and ultimately denied the request for injunctive relief. See Aug. 27, 2009 Order. Thereafter, the plaintiffs moved for leave to conduct jurisdictional discovery, see Pls.' Mot. Re: Discovery, which the defendants oppose, see Defs.' Opp'n Re: Discovery. The plaintiffs also filed multiple motions for leave to file supplemental declarations of various plaintiffs in an effort to establish standing. See Pls.' Mot. to Supplement I, Pls.' Mot. to Supplement II, and Pls.' Mot. to Supplement III. The defendants have moved unopposed for a protective order to be entered in this case. See Motion for a Protective Order.

## II. STANDARD OF REVIEW

In deciding a motion to dismiss for lack of subject-matter jurisdiction under Federal Rule of Civil Procedure 12(b)(1), a court must "accept all factual allegations in the complaint as true." Jerome Stevens Pharms., Inc. v. FDA, 402 F.3d 1249, 1253 (D.C. Cir. 2005) (quoting United States v. Gaubert, 499 U.S. 315, 327 (1991)). A court is not limited to the allegations set forth in

the complaint when assessing a Rule 12(b)(1) motion, but "may consider materials outside of the pleadings in deciding whether to grant a motion to dismiss for lack of jurisdiction[.]" Id. Moreover, under Rule 12(b)(1), "[i]t is to be presumed that a cause lies outside [a federal courts'] limited jurisdiction," Kokkonen v. Guardian Life Ins. Co. of Am., 511 U.S. 375, 377 (1994) (citations omitted), unless the plaintiffs establish by a preponderance of the evidence that the Court has jurisdiction, see Hollingsworth v. Duff, 444 F. Supp. 2d 61, 63 (D.D.C. 2006).

### III. LEGAL ANALYSIS

Article III of the federal Constitution extends judicial power to courts only in situations involving "Cases" or "Controversies." U.S. Const. art. III, § 2. This jurisdictional limitation imposes the requirement that a plaintiff must have standing to pursue a matter in federal court, Nat'l Treasury Employees Union v. United States, 101 F.3d 1423, 1427 (D.C. Cir. 1996), which requires the presence of the following three prerequisites: "(1) injury in fact, (2) causation, and (3) redressability," Young America's Foundation v. Gates, 573 F.3d 797, 799 (D.C. Cir. 2009) (citing Lujan v. Defenders of Wildlife, 504 U.S. 555, 560-61 (1992)).

#### A. **The Plaintiffs' Request for Leave to File Supplemental Declarations in Support of Standing**

Subsequent to the defendants moving for dismissal of this action, the plaintiffs filed multiple motions for leave to submit supplemental information in the form of declarations by members of Mercury-Free in their effort to demonstrate that at least one plaintiff, if not all of them, possess the requisite standing to maintain this action. See Pls.' Mot. to Supplement I; Pls.' Mot. to Supplement II; Pls.' Mot. to Supplement III. The defendants oppose these motions, contending that the plaintiffs must demonstrate standing "based on the complaint at the time the complaint was filed." Defs.' Opp'n Re: Leave to Supplement at 3. The defendants' position is inaccurate because the law in this Circuit does, in fact, permit plaintiffs to submit post-complaint

affidavits to demonstrate standing. See, e.g., Am. Library Ass'n v. FCC, 401 F.3d 489, 494 (D.C. Cir. 2005) (indicating that where jurisdictional questions exist, a court may seek supplemental briefing); D&F Alfonso Realty Trust v. Garvey, 216 F.3d 1191, 1194 (D.C. Cir. 2000) (indicating that the petitioners overcame a standing challenge when "afforded . . . the opportunity [after oral argument] to submit affidavits supporting its allegations"). Moreover, the Court can also look outside the four corners of the complaint to determine its jurisdiction. Jerome Stevens Pharms., 402 F.3d at 1253. Accordingly, the Court will grant the plaintiffs' three motions for leave to supplement the record and consider the additional information in assessing whether the Court has Article III jurisdiction to consider their claims.

**B. The National Vaccine Injury Compensation Act Does Not Confer Standing in the Absence of Satisfying the Traditional Standing Requirements**

The plaintiffs contend that they have standing to bring this action because the National Vaccine Injury Compensation Act ("Vaccine Act"), 42 U.S.C. §§ 300aa-10–300aa-34 (2006), through its citizen suit provision, states that "[a]ny person may commence in a district court of the United States a civil action on such person's own behalf against the Secretary where there is alleged a failure of the Secretary to perform any act or duty upon this part." 42 U.S.C. § 300aa-31; see also Pls.' Mem. Re: Discovery at 8. On the other hand, the defendants, relying upon Lujan, 504 U.S. 555, contend that the traditional requirements of standing are not present in this case, and the statutory provision relied upon by the plaintiffs does not confer standing in the absence of satisfying the traditional standing requirements. See Defs.' Opp'n Re: Discovery at 19-20. The Court finds that the defendants have the stronger position.

In Lujan, the Supreme Court determined that the plaintiffs lacked standing despite their reliance on a citizen suit provision similar to the one relied upon by the plaintiffs here. 504 U.S. at 571-74; see also Common Cause v. FEC, 108 F.3d 413, 419 (D.C. Cir. 1997) (indicating that a

“citizen suit” provision “does not confer standing; it confers a right to sue upon parties who otherwise already have standing”). Similar to the citizen suit provision in Lujan, 42 U.S.C. § 300aa-31 authorizes suits against the government for violations of the Vaccine Act, but it does not dispense with the requirement that the plaintiffs must demonstrate that they have standing to bring such an action in federal court. 42 U.S.C. § 300aa-31.

The plaintiffs’ reliance on FCC v. Akins, 524 U.S. 11 (1998), and its similar citizen suit provision does not alter this obligation. See Pls.’ Reply Re: Discovery at 11-18. In Akins, the Supreme Court did not require that a plaintiff demonstrate a “prudential” injury in fact. See Akins, 524 U.S. at 19. Rather, the Court held that the language of the statute under dispute in Akins, 2 U.S.C. § 437g(8)(A), “cast the standing net broadly-beyond the common-law interest and substantive statutory rights upon which ‘prudential’ standing traditionally rested.” Id. at 19 (finding the statutory language indicates that any “aggrieved” party may bring suit). The Court additionally ruled that, even if the narrower traditional requirements for standing were necessary, the Federal Election Campaign Act (“Election Act”) required publication of certain information and the denial of such publication constituted an injury in fact. Id. at 21 (stating that “[t]he ‘injury in fact’ that respondents have suffered consists of their inability to obtain information . . . the statute requires that [the American Israel Public Affairs Committee] make public.”).

Likewise, the plaintiffs here attempt to bring themselves within the scope of Akins by relying on the defendants’ alleged denial of information as the basis for creating an injury in fact.

Specifically, they assert that “the information that the Plaintiffs seek to have the Defendants provide to the public is clear meaningful information on the presence and level of added mercury in each vaccine dose, without which, the individual’s ability to give ‘informed consent’ does not exist.” Pls.’ Reply Re: Discovery at 16. The plaintiffs’ position is not persuasive. The Supreme

Court held in Akins that the denial of certain political campaign information constituted an injury in fact, but the case does not stand for the blanket proposition that any denial of information to the public creates an injury in fact for Article III purposes, which this Court would have to find to be the case in order to find an injury in fact in this situation. 524 U.S. at 21. The Vaccine Act does not create an explicit right to information as the Election Act does, as the Court found existed in Akins. Because the Court finds that the Vaccine Act does not create an injury in fact resulting from the non-disclosure of information, nor does it otherwise confer standing through its citizen suit provision in the absence of satisfying the traditional requirements for Article III standing, the Court must determine whether these traditional standing requirements are met.

**C. Mercury-Free's Theory of Organizational Standing**

Mercury-Free, an organizational plaintiff, brings this action on behalf of the interests of its members. See Compl. ¶¶ 3-7. For an organization to have standing to bring suit on behalf of its members, it must satisfy three requirements: "(a) its members would otherwise have standing to sue in their own right; (b) the interests it seeks to protect are germane to the organization's purpose; and (c) neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit." Hunt v. Wash. State Apple Advertising Comm'n, 432 U.S. 333, 343 (1977). The defendants do not contend that the plaintiffs do not satisfy the second and third elements of organizational standing, but they do contend that Mercury-Free does not satisfy the first element because the plaintiffs have not demonstrated that at least one of its members would "have standing to sue in their own right." Defs.' Reply at 7 (quoting Pls.' Opp'n at 9). Mercury-Free has submitted affidavits from several of its members, see, e.g., Pls.' Reply Re: Discovery, Ex. 18 (Decl. of Micah Sanderson); id., Ex. 19 (Decl. of Jennifer Krekeler); id., Ex. 30 (Decl. of Vergie Poore), and therefore to determine whether Mercury-Free has established

organizational standing, the Court must evaluate whether any of the Mercury-Free members who have submitted affidavits would independently have standing to bring this action.<sup>7</sup>

#### **D. Three Categories of Injuries Asserted by the Plaintiffs**

Numerous Mercury-Free members have filed declarations alleging injuries caused by the defendants' failure to eradicate mercury-based compounds from use in all vaccines. Four additional and individually named plaintiffs have also been joined as parties in this case: plaintiffs Lisa Sykes, Dr. Mark R. Geier, David R. Geier, and Paul King, PhD. All of the plaintiffs' alleged injuries appear to fall into three categories: (1) plaintiffs who fear the harmful

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<sup>7</sup> The plaintiffs also theorize that Mercury-Free has standing based on the probability that at least one of its unnamed members is likely to be harmed. See Pls.' Mem. Re: Discovery at 2-4. In conjunction with its request for jurisdictional discovery, the plaintiffs performed a rudimentary statistical calculation to support its conclusion that "not less than 8,000 women" of the Women's Division of the United Methodist Church ("Church") – which it labeled as an "affiliate" of Mercury-Free – are of childbearing age at any given time. Id. at 3. Through jurisdictional discovery the plaintiffs seek information that could provide it the ability to demonstrate the likelihood that one of these unnamed members of the Church will suffer harm if the relief it is requesting is not granted. Id. at 4.

Putting aside the defendants' seemingly meritorious position that standing cannot be based on an affiliate of the plaintiff, see Defs.' Opp'n Re: Injunction; Pls.' Mot. Re: Discovery at 16, the plaintiffs are mistaken that standing can be based on the argument that an unnamed member of its organization is likely to be harmed. The Supreme Court directly addressed the issue of probabilistic standing based on potential future injuries to unnamed members of an organization in Summers v. Earth Island Inst., \_\_\_ U.S. \_\_\_, 129 S.Ct. 1142 (2009). In Summers a group of environmental organizations filed suit to prevent the United States Forest Service from enforcing regulations that exempted various land management decisions from the notice, comment and appeals process that otherwise would apply. Id. at 1147. The largest of the plaintiff organizations, the Sierra Club, asserted in its pleadings that it had 700,000 members nationwide who use and enjoy national forests that are affected by the government's land management policies. Id. at 1151. The plaintiffs in Summers argued that they could base standing on the fact that because so many of their members use and enjoy the national forests it was highly likely that one or more of them would suffer harm. Id. The Supreme Court rejected this argument, stating that "[t]his novel approach to the law of organizational standing would make a mockery of our prior cases, which have required plaintiff-organizations to make specific allegations establishing that at least one identified member had suffered or would suffer harm." Id. The Court therefore held that an organization cannot base standing on the allegation that there is a "statistical probability" that one of its members would have standing, instead ruling that there must be at least one named and identified member with individual standing for an organization to have standing. Id. at 1152.

Thus, this Court must look only at whether named and identified members of Mercury-Free – not unnamed members or organizations affiliated with Mercury-Free – meet the requisite conditions of standing. Accordingly, because the plaintiffs' jurisdictional discovery request is designed to retrieve information to further their probability of harm theory to unnamed persons, the Court finds that the request "would not 'be beneficial to [the] plaintiff's establishment of jurisdiction,' [and therefore,] discovery need not be granted prior to dismissal on jurisdictional grounds." Baptist Mem'l Hosp. v. Johnson, 603 F. Supp. 2d 40, 44 (D.D.C. 2009) (some alterations in original). Consequently, the plaintiffs' Motion for Leave to Conduct Discovery Limited to the Issue of Jurisdiction must be denied, and the defendants' motion for a protective order, which would only have utility if the court permitted discovery to be conducted, is denied as moot.

effects of receiving vaccinations that contain mercury-based compounds, see, e.g., Pls.' Opp'n, Ex. 3C (Decl. of Lisa Sykes ¶ 5); (2) plaintiffs who were injured from exposure to mercury-based compounds contained in vaccines, see, e.g., Pls.' Mot. to Supplement III, Ex. B (Decl. of Tamara Dudek at 2-3) (alleging that a vaccine containing Thimerosal caused her miscarriage); and (3) medical professionals who allege that their professional reputations will be harmed absent action being taken by the defendants to address the presence of mercury-based compounds in vaccines, see e.g., Pls.' Opp'n, Ex. 3D (Decl. of Dr. Janet Kern ¶ 10). The Court finds, for reasons stated below, that none of these three categories confers standing on any of the plaintiffs.

**1. Plaintiffs Who Fear Vaccinations that Contain Mercury-Based Compounds**

The plaintiffs allege that many Mercury-Free members are injured by the defendants' denial of their citizens' petition due to the federal government's refusal to ban Thimerosal from all vaccines on the market, which denies them the opportunity to be safely vaccinated. See Pls.' Opp'n at 7. Several Mercury-Free members submitted declarations stating that they are so fearful of being harmed by Thimerosal that they abstain from receiving any vaccinations. See, e.g., Pls.' Opp'n, Ex. 3C (Decl. of Lisa Sykes ¶ 5); id., Ex. 3A (Decl. of Paul King ¶ 7).

Nevertheless, the plaintiffs themselves admit in their pleadings that there are Thimerosal-free alternatives for all available vaccines approved and recommended by the defendants. See Pls.' Opp'n at 4 ("[E]very prophylactic vaccine and biological drug product routinely recommended for population-wide administration to protect the public health is admittedly available in a form that has no added mercury compound in it"). Thus, the defendants respond that the plaintiffs suffered no injury because they could have chosen to receive a vaccine that is Thimerosal-free. Defs.' Mem. at 1-2. The Court agrees with the defendants that if the plaintiffs are able to receive

vaccines that do not contain mercury, then they have not “suffered an ‘injury in fact’” that is “concrete in both a qualitative and temporal sense”, that is “distinct and palpable . . . as opposed to merely abstract”, as well as being “actual or imminent, not ‘conjectural’ or ‘hypothetical.’” Whitmore v. Arkansas, 495 U.S. 149, 155 (1990) (citations omitted).

The plaintiffs respond with two arguments. First, they contend that Thimerosal-free vaccines are not widely available and cannot be found in many clinics, thus causing the plaintiffs injury because they are burdened with delay and uncertainty while searching for Thimerosal-free alternatives. See Pls.' Opp'n at 15. Second, the plaintiffs argue that even if they desire and search out Thimerosal-free forms of the vaccines, they cannot be assured that they will receive a vaccine that is Thimerosal-free "due to the confusion among members of the medical profession" as to whether a particular vaccine contains Thimerosal or other forms of mercury. Pls.' Reply Re: Discovery at 7-8. The Court will address these arguments in turn.

a. Lack of Universal Availability of Mercury-Free Vaccines

Despite conceding that "it is true that alternatives are available," the plaintiffs argue that "patients of a clinic have no effective choice other than to avoid vaccines altogether, because clinics [and doctors' offices] do not generally carry alternatives." Pls.' Opp'n at 15. They have submitted declarations that support their allegations that certain clinics and pharmacies do not carry Thimerosal-free vaccines. See, e.g., Pls.' Reply Re: Discovery, Ex. 4, (Decl. of Cecelia Bowers ¶¶ 3-6) (statement by nurse that there will be no mercury-free vaccines available at a one-day flu shot clinic at a church in Midlothian, Virginia). But this does not demonstrate a total lack of availability for any one particular member of Mercury-Free or for any particular region of the country. Indeed, a careful review of the plaintiffs' submissions indicates that Thimerosal-free vaccines are available on the market. See, e.g., Pls.' Reply Re: Discovery, Ex. 6, (Decl. of Dr.

Mark Geier ¶ 6) (doctor stating that there was a "significant stock" of both Thimerosal-preserved multi-dose vials and mercury-free single-dose vials at a Safeway Pharmacy in Silver Spring, Maryland). More proof is required to establish standing than merely asserting that some pharmacies or clinics either do not carry, or only carry a small amount, of the mercury-free product that the plaintiffs' seek.

The plaintiffs also theorize that the lack of universal availability of Thimerosal-free vaccines and the delay in acquiring vaccinations caused by seeking alternatives constitutes an injury in fact. Pls.' Opp'n at 13-15 (citing Tummino v. Torti, 603 F. Supp. 2d 519 (E.D.N.Y. 2009)). Again, this position is not persuasive. Tummino, even if controlling in this jurisdiction, does not command such a result. In Tummino, the court held that a group of adolescents were in fact injured by FDA rules that required persons under 16 years of age to get a prescription before obtaining Plan B morning after contraception pills. 603 F. Supp. 2d at 540. This case is inapplicable for two reasons. First, the delay was caused by a government regulation requiring adolescents to schedule appointments with and visit a doctor before obtaining the contraception. Id. Here, all that can be discerned from existing record is that any delay would be caused by the individual choice of a particular clinic or pharmacy to acquire only certain types of vaccines. An individualized choice of this nature cannot be said to be "fairly traceable" to the defendants' conduct, which is a requirement for Article III standing. See Lujan, 504 U.S. at 560-61. Second, with regards to the Plan B contraception at issue in Tummino, rapid access to the pill is essential to its effectiveness, as the pill loses much of its effectiveness within 24 hours of conception, and is rendered nearly useless after 72 hours. 603 F. Supp. 2d at 539. The harm caused by requiring a doctor's visit was quite obvious – it delayed the adolescent from obtaining a pill when there was a limited window of opportunity of that pill's effectiveness. Id. at 540.

Here, the plaintiffs have offered no such evidence as to how they are harmed by the delay in receiving vaccinations resulting from the time it takes to acquire Thimerosal-free vaccines.

Additionally, the plaintiffs have offered no evidence concerning how long any such delay would be because the only evidence the proffer is that isolated clinics or pharmacies in different areas of the country did not carry Thimerosal-free vaccines. In the absence of any proof a named plaintiff would not be able to acquire a mercury-free alternative within the timeframe necessary for a vaccine to have its intended impact, the Court finds that the injury alleged by the plaintiffs resulting from the purported delay in obtaining mercury-free vaccinations is purely speculative.

Given the market availability of mercury-free vaccination alternatives, and it being the plaintiffs' burden to demonstrate standing by asserting an injury in fact, Sierra Club v. EPA, 292 F.3d 896, 898 (D.C. Cir. 2002), which cannot be found with respect to the plaintiffs who assert standing based on their fear of the harmful effects of receiving mercury-based vaccines, the Court finds that the plaintiffs have not established standing based on this theory.

b. Confusion Among Medical Professionals About Mercury-Free Vaccines

The plaintiffs also contend that they have alleged an injury in fact because they cannot access the Thimerosal-free vaccines due to the confusion among members of the medical profession as to which versions of the flu vaccines are, in fact, mercury-free. Pls.' Reply Re: Discovery at 7-8. To support this contention, the plaintiffs have submitted several affidavits of Mercury-Free members describing their experiences dealing with medical personnel at various clinics and medical offices nationwide that distribute some form of the flu vaccine. See id., Exs. 5-30. The plaintiffs allege that some medical professionals were unable to indicate to them whether certain brands or types of vaccines contained a mercury-based compound. Id. Mercury-Free member Nancy Potts, for example, describes an encounter she had with a nurse at a CVS

MinuteClinic in New Jersey, when she was told that the vaccine did not contain mercury, but instead contained Thimerosal. Id., Ex. 14 (Decl. of Nancy Potts ¶ 3e). Ms. Potts points out that this information was erroneous because Thimerosal is a mercury-based compound. Id. Similarly, plaintiff Lisa Sykes indicates that she conducted an “investigation” of four Richmond, Virginia pharmacies “to see what advice [she] would be given as a woman of child-bearing age regarding the flu shot.” Id., Ex. 11 (Decl. of Lisa Sykes ¶ 10). She contends that she received inaccurate information from pharmacy personnel about whether certain vaccines contain mercury and was advised that it was safe for her to take a vaccine that contained Thimerosal if she were pregnant. Id., Ex. 11 (Decl. of Lisa Sykes ¶¶ 54-56). Plaintiff Sykes indicates that the information she received was erroneous. Id.

Even assuming the truth of these declarations, for several reasons such allegations do not confer standing to the plaintiffs for the purpose of bringing claims against the defendants named in this case. First, the plaintiffs went to the clinics as informed patients, believing the medical advice they would ultimately receive would be untrue. They are therefore unable to establish an injury in fact based on having received the purported erroneous information, absent any allegation that they relied on it and that injury resulted. The plaintiffs' mere concern about whether some other unidentified and uninformed person might receive erroneous information in the future and may then receive a mercury-based vaccine that might result in harm, see, e.g., id., Ex. 26 (Decl. of Sarah Cooleen at 3-4) (“I believe that only by fully disclosing what is in vaccines will women be able to make fully informed decisions about themselves and their unborn children. Women are not being protected when they are not fully informed about mercury in vaccines.”), is much too tenuous to establish an injury in fact for constitutional purposes because it is not sufficiently “concrete in both a qualitative and temporal sense,”

“‘distinct and palpable,’ ... as opposed to merely ‘[a]bstract’” nor is it “actual or imminent, not ‘conjectural’ or ‘hypothetical.’” Whitmore, 495 U.S. at 155 (citations omitted) (alteration in original). Additionally, the alleged injury in fact is not “fairly trace[able] to the challenged action of the defendant[s]” named in this case, as it is “the result [of] the independent action of some third party not before the court.” Lujan, 504 U.S. at 560 (some alterations in the original).

The plaintiffs also contend that the defendants are liable for inadequate labeling of Thimerosal vaccines that do not enable “members of the public, such as those who are members of [Mercury-Free, to be] warned of the potential dangers posed by Thimerosal to unborn children.” Pls.’ Reply Re: Discovery at 8. Again, an organization cannot base standing on injury to its unnamed members or members of the public at large. See Summers, \_\_\_ U.S. at \_\_\_, 129 S.Ct. at 1152. Without any allegations that inadequate labeling resulted in harm to either the organizational plaintiff or the named individual plaintiffs personally, this theory also does not confer standing on any of the plaintiffs in this case. Indeed, while not totally unimaginable, at least on the record before the Court here, it is difficult to perceive how members of an organization, whose stated purpose is to reduce and eradicate all use of vaccines containing mercury, see Pls.’ Opp’n, Ex. 4 (Mission), can maintain that their lack of information led to actual injury. This conclusion rings true because the plaintiffs were aware not only of the fact that there are Thimerosal-free vaccines available in the marketplace, but also because it can be readily determined whether a vaccine is mercury-free or not by examining whether it came from a multi-dose vial or a single dose vial. See, e.g., Pls.’ Reply Re: Discovery, Ex. 11 (Decl. of Lisa Sykes ¶¶ 13-54) (stating that she visited four pharmacies and knew at each location whether the vaccines she was being offered contained Thimerosal); id., Ex. 6 (Decl. of Dr. Mark Geier ¶ 6) (indicating that he will dispense vaccines to patients from a single dose vial upon request and he

educated another pharmacist on the composition of the influenza vaccines and learned that the pharmacy he frequented had a significant stock of both mercury-free and Thimerosal vaccines).<sup>8</sup> Standing based on this theory must therefore be rejected.

The plaintiffs further allege that "some pharmacists are loading syringes from multi-dose vials and selling them as single dose shots," and therefore, even the most informed Mercury-Free members cannot be sure that they will receive a mercury-free vaccine. Pls.' Reply Re: Discovery at 5 n.3. This allegation also does not cure the standing problem for two reasons. First, once again, blatant mislabeling and deception by a pharmacist cannot be deemed "fairly traceable" to the actions of the named defendants, a constitutional requirement for Article III standing. Lujan, 504 U.S. at 560-61. Second, this allegation is at odds with the affidavits of other Mercury-Free members who indicated that when they could not be certain whether a vaccine came from a single-dose vial, they chose not to receive the vaccine. See, e.g., Pls.' Reply Re: Discovery, Ex. 20 (Decl. of Julia Whiting at 2-4); id., Ex. 25 (Decl. of Kirsten Ellis ¶ 3); id., Ex. 26 (Decl. of Sarah Cooleen at 3). In the end, none of the members who described their experiences actually agreed to receive a vaccine based on potentially misleading advice from medical professionals. Pls.' Reply Re: Discovery at 7-8. And even assuming the truth of the plaintiffs' allegations that some medical professionals are not well-informed about what vaccines contain mercury and whether they are considered safe for pregnant women, the plaintiffs have nonetheless failed to satisfy their burden of demonstrating that they have suffered an injury in fact that was caused by the named defendants in this case.

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<sup>8</sup> The experience of Dr. Mark Geier, one of the named plaintiffs, directly contradicts both the plaintiffs' theory that mercury-free vaccines are not readily available and their theory that Mercury-Free members would be too confused to determine whether a particular vaccine contains mercury or not. See id., Ex. 6 (Decl. of Dr. Mark Geier).

## 2. Allegations of Past Harm

The plaintiffs also contend that various members of Mercury-Free suffered harm caused by vaccines containing Thimerosal, including autism, miscarriages, and other injuries. See, e.g., Pls.' Opp'n, Ex. 3C (Decl. of Lisa Sykes ¶ 4) (autism); Pls.' Mot. to Supplement III, Ex. B (Decl. of Tamara Dudek at 2-3) (miscarriage). The plaintiffs argue that these past injuries can serve as a basis for standing because

[w]ith regard to prong (a) of the test for organizational standing "its members would otherwise have standing to sue in their own right," plaintiff [Mercury-Free] is a non-profit organization whose membership is comprised primarily of individuals who have suffered injury to themselves and/or their children and wards from Thimerosal-containing vaccines and other added mercury-containing drug products licensed and/or approved by the Defendants.

Pls.' Opp'n at 9 (emphasis added); id. at Exs. 3A-3C. The defendants respond that because the "plaintiffs are not seeking damages[,] ... allegations of past injury alone are insufficient" to create standing. Defs.' Reply at 5-6. Again, even assuming the truth of plaintiffs' allegations of injuries suffered from past use of vaccines containing Thimerosal, such harm still cannot serve as the basis of standing to pursue this lawsuit because the plaintiffs seek relief that is prospective in nature, i.e., not relief that would remedy their past harm. Specifically the plaintiffs seek an injunction requiring the defendants to suspend or revoke the licenses of all drugs and biological products containing a mercury-based preservative, bar the use of such vaccines, and recall any vaccines already in the marketplace. Compl. at 29-30. Because the plaintiffs have not "show[n] that [the defendant's] actions have caused them some concrete injury that th[e] declaratory and injunctive relief [they seek] will redress," they cannot establish standing. Cruz v. Am. Airlines, Inc., 356 F.3d 320, 328 (D.C. Cir. 2004) (citing Fla. Audubon Soc'y v. Bentsen, 94 F.3d 658, 663-64 (D.C. Cir. 1996)) (holding that plaintiffs who lost luggage during airline travel and who

sought an injunction against prospective enforcement of airline's policy of refusing compensation to passengers who do not file timely claims did not have standing unless they could demonstrate that there was a concrete and immediate threat of suffering such harm again in the future); see also City of Los Angeles v. Lyons, 461 U.S. 95, 105-06 (1983) (finding that plaintiff who was stopped by police and held in a chokehold would need to demonstrate he was under a real and immediate threat of being held in chokehold again to have standing to seek injunction declaring the practice illegal). The affidavits submitted by Mercury-Free members detailing allegations of injuries suffered to themselves or their children as a result of past inoculation of vaccines containing Thimerosal do not create standing in an action for prospective injunctive relief. This result is compelled in the absence of the plaintiffs demonstrating that they face a concrete and immediate threat of being harmed by vaccines containing Thimerosal again in the future.

### **3. Injuries to the Reputation of the Medical Profession Plaintiffs**

The plaintiffs also contend that its medical professional members suffer ongoing harm to their reputation because of the defendants' inability to guarantee that drug and biological products that their medical professional members provide are safe. Specifically, the plaintiffs allege that

the member physicians and researchers, have suffered injury to their reputation due to the damage done to the profession by the increasing evidence that the FDA has not been assuring that vaccines which these professionals have administered . . . are safe, a phenomenon causing major concern according to the current issue of the New England Journal of Medicine, as cited previously.

Pls.' Opp'n at 15. Essentially, even if the plaintiffs' allegations are accepted as true, this theory offers nothing more than a generalized grievance on behalf of the medical community, which cannot serve as the basis for finding that the plaintiffs named in this lawsuit have standing. See

Lujan, 504 U.S. at 575-76 (“an injury amounting only to the alleged violation of a right to have the Government act in accordance with law [is] not judicially cognizable because ‘assertion of a right to a particular kind of Government conduct, which the Government has violated by acting differently, cannot alone satisfy the requirements of Art. III without draining those requirements of meaning.’” (citations omitted)). But, more to the point, the plaintiffs' allegations are “[p]urely speculative or conclusory assertions of the consequences of the alleged stigma [and accordingly] do not satisfy the Supreme Court’s requirement for specific, concrete facts demonstrating a particularized injury.” Alamo v. Clay, 137 F.3d 1366, 1370 (D.C. Cir. 1998). For all of these reasons, the Court finds that the individual plaintiffs have failed to provide specific and concrete facts of any specific harm that amounts to an injury in fact sufficient to confer organizational standing to Mercury-Free.

#### **E. The Individual Plaintiffs**

Several of the plaintiffs are individuals who have brought this action on their own behalf, however, for the following reasons, none of these individuals have standing to maintain this lawsuit either.

##### **1. Lisa Sykes**

Plaintiff Lisa Sykes has alleged two injuries that fall into two of the previously addressed categories: a claim for past harm, Pls.' Opp'n, Ex. 3C (Decl. of Lisa Sykes ¶¶ 4-6) (her child suffers from autism), and a claim that she is unable to receive vaccinations without fear of being harmed by mercury, Pls.' Reply Re: Discovery, Ex. 11 (Decl. of Lisa Sykes ¶ 10). For the same reasons that these arguments failed to establish standing for the Mercury-Free members discussed earlier in this opinion, plaintiff Lisa Sykes does not have standing to maintain this lawsuit.

**2. Paul King**

Plaintiff Paul King also alleges harm previously addressed, i.e., he "do[es] not trust the representations that the influenza vaccine is safe" and thus refuses to receive any vaccinations due to the defendants' refusal to remove all vaccines containing mercury-based preservatives from the market. See Pls.' Opp'n, Ex. 3A (Decl. of Paul King) ¶¶ 1, 2, 7, 8. Again, for the reasons discussed above, plaintiff King has also failed to establish that he has standing to maintain this action.

**3. David Geier**

Plaintiff Geier has submitted no affidavit describing how he has been injured by the defendants, nor were any of his alleged injuries referenced in the plaintiffs' pleadings. Accordingly, he has also not established that he has standing to maintain this action.

**4. Dr. Mark Geier**

Dr. Mark Geier is a practicing medical doctor and one of the founding members of Mercury-Free. Pls.' Reply Re: Discovery, Exs. 7-8 (Decl. of Dr. Mark Geier ¶¶ 1, 2). Plaintiff Geier alleges that the defendants' refusal to remove vaccines containing Thimerosal from the market injures him because it puts him at risk to increased legal liability. Specifically he states:

I face a significant risk of liability for any injury that should occur to an unborn child while under my care. Due to the poor information generated with the approval of the Secretary of Health and Human Services and the appalling ignorance of healthcare providers about the mercury content of influenza vaccines and the consequences thereof, I face a significant increase in potential liability due to the extremely high probability that several of my pregnant women patients will receive a Thimerosal-preserved influenza vaccine at drug stores and clinics over which I have no control, despite any effort I may make to inform my patients.

Id., Ex. 8 (Decl. of Dr. Mark Geier ¶ 19).

Again, to meet the injury-in-fact requirement in this Circuit, plaintiff Geier's alleged injury must be "actual or imminent, not conjectural or hypothetical." Lujan, 504 U.S. at 560 (citations omitted). Increased exposure of civil liability does not satisfy this requirement for the following reasons. First, plaintiff Geier fails to explain how he could be subject to liability for an injury one of his patients may suffer as a result of receiving vaccinations from another health care provider. Moreover, any civil liability that plaintiff Geier faces is neither "actual" nor "imminent," but purely "conjectural," as it is based on nothing more than theoretical possibility. Id. The Second Circuit's reasoning in Port Washington Teachers' Ass'n v. Board of Education is instructive on this point. 478 F.3d 494 (2d Cir. 2007). There, the plaintiffs alleged that compliance with a school board's policy requiring school social workers to report student pregnancies to the school principal, district superintendent, and the student's parents constituted an injury in fact because it would expose the social workers to civil liability. Id. at 499. The Second Circuit rejected this argument on the grounds that "[b]ecause the plaintiffs have not established that civil liability or professional discipline is actual or imminent, the theoretical possibility that either might occur does not amount to injury in fact." Id. at 500 (citing Lujan, 504 U.S. at 564). Plaintiff Geier's alleged injury of exposure to civil liability suffers from the same frailty, as he alleges only that he might be sued by some unknown patient at some unknown time in the future for the potential acts of a third party. Thus, plaintiff Geier has failed to allege an injury in fact and thus has also failed to establish that he has standing to maintain this lawsuit.

#### IV. CONCLUSION

For the reasons set forth above, the plaintiffs' three motions for leave to supplement the record are granted, the plaintiffs' motion for leave to conduct discovery is denied, the defendants' motion for a protective order is denied as moot, and the defendants' motion to dismiss the

complaint is granted due to the named plaintiffs' failure to establish that any of them have standing to maintain this action.<sup>9</sup>

\_\_\_\_\_/s/\_\_\_\_\_  
REGGIE B. WALTON  
United States District Judge

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<sup>9</sup> Orders consistent with this Memorandum Opinion were issued on March 31, 2010, and June 29, 2010. A Second Amended Order accompanies this Amended Memorandum Opinion.